ANNEX 4

Stabilly Repaid #1356 SU010398 capsule

ACCO. USA





Analyses Report

Management · Information Laboratory System

Global Pharmaceutical Sciences - Italy

Submission (d: 117733 Sample ID (Request No.): 20023347

User sample ID (lot): [83G02

Sample Type: SU010398 (PNU290940AD) CAPSULE 50 MG

Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 25^C/60% U.R. Time Label: 18 MONTHS Preparation purpose: STABILITY Request Type: STABILITY Stability Study: 183G02

Condition: APPROVED Status: COMPLETE

Method	Controls	Results	Vers.	M.U.	Spec? Low	rer lim	Lower lim Upper lim	Book-Data Analyses	Analyst	Verifier
083GCC02#00	CAPSULE APPEARANCE	0=UNCHANGED	•	¥					CAPPUCCIO	MACCARI
	CAPSULE COLOR	0=UNCHANGED	-	B					CAPPUCCIO	MACCAR
	CONTENT APPEARANCE	0=UNCHANGED	-	¥					CAPPUCCIO	MACCARI
	CONTENT COLOR	0=UNCHANGED	*-	Ħ					CAPPUCCIÓ	MACCARI
	SMELL	0=UNCHANGED	-	Ħ					CAPPUCCIO	MACCARI
083GTI01#01_S	(HPLC TITER) SAMPLE#1	100.0	-	*	0.08	- 96	90,060 - 110,000	15545/86-JAN 2003	CAPPUCCIO	MACCAR
	(HPLC TITER) SAMPLE#2	101.0	-	*	900	8	90.000 - 110.000	15545/86-JAN 2003	CAPPUCCIO	MACCARI
	(HPLC TITER) SAMPLE#3	. 9,001	-	%	90.0	90.000 - 110.000	110,000	15545/86-JAN 2003	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	100.53	_	×	0.06	90,000 - 110,000	110.000	15545/86-JAN 2003	CAPPUCCIO	MACCARI
083GSC01#00	TOTAL CORRELATED SUBSTANCES	0.77	•-	*	16	12		15545/86- JAN 2003	CAPPUCCIO	MACCARI
	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	-	*	A Traceraction	/ 2	23	15545/86- JAN 2003	CAPPUCCIO	MACCAR
083GKF01#00	(HUMIDITY) SAMPLE #1	oj.	-	×	A	Q)	45	15545/86- JAN 2003	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #2	1.8	-	×	SO CONTROL	600	_	15545/86- JAN 2003	CAPPUCCIO	MACCARI
٠	(HUMIDITY) SAMPLE#3	1.8	_	38	EK.	į, į	8.8	15545/88- JAN 2003	CAPPUCCIO	MACCARI
	AVERAGE HUMIDITY	1.83	_	38	a	Sugar	•••	15545/86- JAN 2003	CAPPUCCIO	MACCAR

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Analyses Report

Laboratory Information Management System

Global Pharmaceutical Sciences - Italy

Submission Id: 117733 Sample

Request Type: STABILITY

Condition:

Sample ID User t	Sample ID (Request No.); 20023347 User sample ID (lot); 183G02 Sample Type: SU010398 (PNU290940AD) CAPSULE 50 MG	J290940AD) CAR	SULE 50		Storage C Storage Ti	Stability Study: 183602 Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 25°C/60% U.R. Time Label: 18 MONTHS Preparation purpose: STABILITY	GO2 ml PLASTIC AC/60% U.R MONTHS ABILLITY	; BOTTLE	APPROVED Shitus: COMPLETE	۵
Samples Notes:										
Method	Controls	Results	Vers.	M.U.	Spec?	Lower lim	Lower lim Upper Jim	Book-Data Analyses	Analyst	Verifier
083GDS01#01	SAMPLE#1	109.0	-	36		. 80.000		15545/86- JAN 2003	CAPPUCCIO	MACCARI
	SAMPLE#2	102.2	-	36		80.000		15545/86- JAN 2003	CAPPUCCIO	MACCAR
	SAMPLE#3	106.8	-	*		80.000		15545/86- JAN 2003	CAPPUCCIO	MACCARI
	SAMPLE#4	104.3	-	9£		80.000		15545/86- JAN 2003	CAPPUCCIO	MACCARI
	SAMPLE#5	106.5	-	*		80,000		15545/86- JAN 2003	CAPPUCCIO	MACCARI
	SAMPLE#6	105.0	-	36		80,000		15545/86- JAN 2003	CAPPUCCIO	MACCARI
	DISSOLUTION	105.63	-	\$€		80.000		15545/86- JAN 2003	CAPPUCCIO	MACCAR
	STANDARD DEVIATION	2,342	-	std-1				15545/86- JAN 2003	CAPPUCCIO	MACCAR
	C.V.	2.22	.	38				15545/86- JAN 2003	CAPPUCCIO	MACCARI
	MIN. DISSOLUTION VALUE 102.2	102.2	-	38		80.000		15545/86- JAN 2003	CAPPUCCIO	MACCARI
	MAX. DISSOLUTION VALUE 109.	109.0	-	*		80.000		15545/86- JAN 2003	CAPPUCCIO	MACCARI

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Analyses Report

Management Information. Laboratory System

Global Pharmaceutical Sciences - Italy

Sample ID (Request No.) ; 20023347 Submission (d: 117733

User sample ID (lot): 183G02

Sample Type: SU010398 (PNU290940AD) CAPSULE 50

Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 25^C/60% U.R. Time Label: 18 MONTHS

Preparation purpose: STABILITY

Request Type: STABILITY

Stability Study: 183G02

Condition: APPROVED

COMPLETE Status:

Samples Notes:

083GC02#00, component: CAPSULE APPEARANCE Observations on the Method Opaque brick red colored hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GC01#00, component: IMPURITIES NOT LESS THAN 0.05%

Total correlated substances; 0,77

Area %

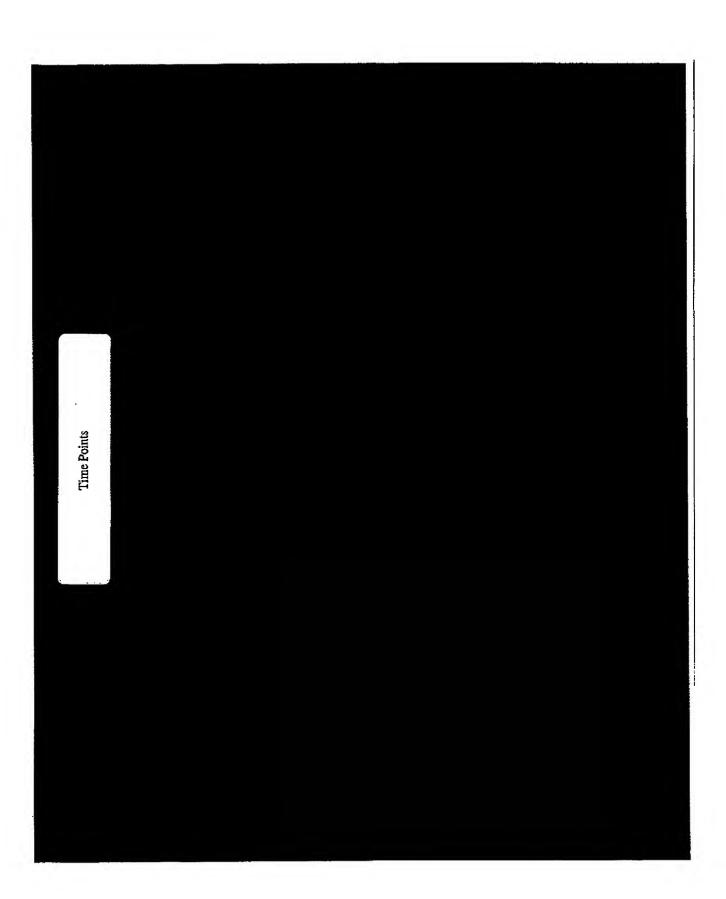
0.65 0.94 0.94 1.16 1.28 1.70 1.70

0.00 0.10 0.00 0.00 0.00 0.00 0.11

INTERNAL USE ONLY

SAMPLE APPROVED BY: GIUSEPPE MACCARI APPROVE DATE: 26-may-2003

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Integrated Analytical Bulletin

Information Management System Laboratory

Pharmaceutical Development

Submission Id: 116558 Sample ID (Request No.); 20021516 User sample ID (lot); 183G02

Sample Type: SU010398 (PNU290840AD) CAPSULE 50 MG Sample Date: 31/05/2002

Batch Manufacture Date: 17/05/2001 Stability Study: 183G02 Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 25°C/60% U.R. Time Label: 12 MONTHS Preparation purpose: STABILITY

Condition: APPROVED

Status: COMPLETE

Stabillty Study Start Date: 31/05/2001

S.P.N. 2001005 - Manufacturer PD/PHARMACIA Nerviano - API Batch (A)5975-MTM-0002 Samples Notes:

Method	Controls	Results	M.U.	Spec? Lower iim Upper li	Lower IIm Upper IIm Book-Data Analyses	Analyst	Verifier
0836CO02#0	CAPSULE APPEARANCE	0=UNCHANGED	茎		15545/27- JUN 2002	CAPPUCCIO	MACCARI
6	CAPSULE COLOR	0=UNCHANGED	兹		15545/27- JUN 2002	CAPPUCCIO	MACCARI
	CONTENT APPEARANCE	0=UNCHANGED	Ħ		15545/27- JUN 2002	CAPPUCCIO	MACCARI
	CONTENT COLOR	0=UNCHANGED	Ħ		16545/27- JUN 2002	CAPPUCCIO	MACCARI
	SMELL	0=UNCHANGED	¥		15545/27- JUN 2002	CAPPUCCIO	MACCAR
овзстіот#01	(HPLC TITER) SAMPLE#1	100.06	*	90,000 - 110,000	15545/27~JUN 2002	CAPPUCCIO	MACCARI
νo _ι	(HPLC TITER) SAMPLE#2	99.11	%	90,000 - 110,000	15545/27~JUN 2002	CAPPUCCIO	MACCAR
	(HPLC TITER) SAMPLE#3	98.04	%	90,000 - 110,000	15545/27-JUN 2002	CAPPUCCIO	MACCARI
	AVERAGE TITER (HPLC)	99.07	%	30.000 - 110.000	15545/27-JUN 2002	CAPPUCCIO	MACCARI
383GSC01#0	083GSC01#0 TOTAL CORRELATED SUBSTANCES	0.80	%	STATE OF THE PARTY	15545/27- JUN 2002	CAPPUCCIO	MACCARI
•	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	%	Sign A	15545/27- JUN 2002	CAPPUCCIO	MACCARI
083GKF01#00	083GKF01#00 (HUMIDITY) SAMPLE #1	2.20	%	222	15545/27- JUN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SAMPLE #2	2.25	%	6000	15545/27- JUN 2002	CAPPUCCIO	MACCARI
	(HUMIDITY) SÄMPLE #3	2.25	%	JUL 2006	15545/27- JUN 2002	CAPPUCCIO	MACCARI
	AVERAGE HUMIDITY	2.23	88	25	15545/27- JUN 2002	CAPPUCCIO	MACCARI
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Integrated Analytical Bulletin

Management Information Laboratory System

Pharmaceutical Development

Sample Date: 31/05/2002 Sample ID (Request No.) ; 20021516 User sample ID (lot) ; 183G02 Submission Id: 116558

Sample Type: SU010398 (PNU290940AD) CAPSULE 50

Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 25°C/60% U.R. Batch Manufacture Date: 17/05/2001 Stability Study: 183G02

Time Label: 12 MONTHS Preparation purpose: STABILITY

Condition: APPROVED

COMPLETE Status:

Stability Study Start Date: 31/05/2001

S.P.N. 2001005 - Manufacturer PD/PHARMACIA Nerviano - API Batch

Samples Notes:

(A)5975-MTM-0002

MACCARI Verifier CAPPUCCIO Analyst Lower lim Upper lim Book-Data Analyses 5545/27- JUN 2002 15545/27-JUN 2002 5545/27-JUN 2002 15545/27- JUN 2002 15545/27- JUN 2002 15545/27- JUN 2002 5545/27- JUN 2002 5545/27-JUN 2002 15545/27- JUN 2002 5545/27-JUN 2002 5545/27- JUN 2002 5545/27- JUN 2002 5545/27- JUN 2002 5545/27- JUN 2002 15545/27- JUN 2002 5545/27- JUN 2002 15545/27- JUN 2002 80.000 80,000 80.000 80,000 80.000 80.000 80.000 80.000 Spec? M.U. Std-1 ¥ Ħ 젊 ¥ Ħ IN LIMITS IN LIMITS IN LIMITS ABSENT ABSENT ABSENT Results 100.16 100.16 96.76 92.80 95.91 99.02 97.23 2,75 2.67 STAPHYLOCOCCUS AUREUS MAX. DISSOLUTION VALUE TOTAL AEROBIC BACTERIA MIN. DISSOLUTION VALUE STANDARD DEVIATION ENTEROBACTERIA ESCHERICHIA COLI DISSOLUTION SALMONELLA SAMPLE#5 SAMPLE#2 SAMPLE#4 SAMPLE#6 SAMPLE#3 SAMPLE# Controls 083GMC01#0 083GDS01#0 Method

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Integrated Analytical Bulletin

Management Information Laboratory System

Condition: APPROVED

Status: COMPLETE

Pack Type: 30 ml PLASTIC BOTTLE

Batch Manufacture Date: 17/05/2001 Stability Study: 183G02 Storage Condition: 25/C/60% U.R. Time Label: 12 MONTHS

Preparation purpose: STABILITY

Pharmaceutical Development

Sample ID (Request No.); 20021516 User sample ID (lot); 183G02 Submission Id: 116558

Sample Date: 31/05/2002

Sample Type: SU010398 (PNU290940AD) CAPSULE 50 MG

Stability Study Start Date: 31/05/2001

S.P.N. 2001005 - Manufacturer PD/PHARMACIA Nerviano - API Batch (A)5975-MTM-0002

Samples Notes:

083GCO02#00, component: CAPSULE APPEARANCE Observations on the Method Opaque brick red colored shaped hard gelatin capsule containing yellow-orange colored powder

083GDS01#01, component: DISSOLUTION Observations on the Method

Average dissolution at 15 minutes: 96.05% (interval: 90.25%-100.16%) Average dissolution at 45 minutes: 98.18% (interval: 91.95%-101.57%)

Total bacteria count < 10 Ufc/g (Report No. 02.9470)

Observations on the Method

083GMC01#01, component: TOTAL AEROBIC BACTERIA

083GMC01#01, component: ENTEROBACTERIA Observations on the Method

Enterobacteria < 10 Ufc/g (Report No. 02.9470)

083GMC01#01, component: ESCHERICHIA COLI Observations on the Method

Report No. 02.9470

083GMC01#01, component: FUNGI Observations on the Method

Fungi (Yeasts + Molds) < 10 Ufc/g (Report No. 02.9470)

083GMC01#01, component: SALMONELLA Observations on the Method

Report No. 02,9470

083GMC01#01, component: STAPHYLOCOCCUS AUREUS Observations on the Method

Report No. 02.9470

083GC01#00, component: IMPURITIES NOT LESS THAN 0.05% Observations on the Method

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Integrated Analytical Bulletin

Management System Information Laboratory

Condition: APPROVED

Status: COMPLETE

Pack Type: 30 ml PLASTIC BOTTLE

Batch Manufacture Date: 17/05/2001 Stability Study: 183G02 Storage Condition: 25^C/60% U.R. Time Label: 12 MONTHS Preparation purpose: STABILITY

Pharmaceutical Development

Sample ID (Request No.); 20021516 Submission Id: 116558

Sample Date: 31/05/2002 User sample ID (lot): 183G02

Sample Type: SU010398 (PNU290940AD) CAPSULE 50

Stability Study Start Date: 31/05/2001

S.P.N. 2001005 - Manufacturer PD/PHARMACIA Nerviano - API Balch (A)5975-MTM-0002

Samples Notes:

083GC01#00, component: IMPURITIES NOT LESS THAN 0.05% Observations on the Method

Total correlated substances: 0.80%

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0.05 0.09 0.30 0.94 1.06 1.09 1.28 1.28 1.29 0.7. 0.91

(SU 11248)

0.14 90'0 0.07

Approved by: MACCARI Approval date: 21-jún-2002

Information Information Management System

Report

Sample ID (Request No.) ; 20011710 User sample ID (lot) ; 1885622

Bampia Type: Stortoses (PANZSERAGAD) CAPSULE 50 b/G

Subling Study; 183502

Pack Type EULK
Showye Condition: TIME ZERO
Time Labet TIME ZERO
Preparation purpose: STABILITY

Condition:
APPROVED
States:
COMPLETE

	Controls	Results	M.U.	Spec?	Lower lim	Upper ilm	Upper iim Book-Data Analyses	Analyst	Verifier
1839CO01#0	CESISCOCIFO APPEARANCE	COMPLIANT	3				15685 - JUN 2004	PASTO	MARKANI
1036(20) 901	OBSCIZDIFOI HPLC IDENTIFICATION	POSITIVE	¥				75/35-:JUN 2001	PASTO	MARRAMI
пезатючен	OBSCRIPCION (HPLC TITER) SAMPLE#1	8 k3	*		96,000 - 105,000	105,000	75/25 - JUN 20 PI	PASTO	MARIAHI
5	, (HPLC TITER) SAMPLE#2	· £25	×		95,000 - 105,000	105,090	75K56 - JUN 2001	PASTO	MARIANI
	(HPLC TITER) SAMPLE#3	PR.1	×	,	95.000 -	- 105.000	7585 - JUN 2001	PASTO	MAHAM
	AVERAGE TITER (HPLC)	28.03	*		95,000 - 105,000	105,000	75056 - JUN 2001	PASTO	MARITAN
DESCENDE	OCSGENOTIFIC TOTAL CORRELATED SUBSTANCES 13	1	ж				75/35 - JUN 2001	PASTO	MARINA
-	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	₩.				75355 - JUN 2001	PASTO	MAHAM
DUSCHARDOU	OUDCREDIFOO (HUMIDITY) SAMPLE #1	1.46	×				75/26 - JUN 2001	PASTO	MARMA
	(HUMIDITY) SAMPLE #2	1.63	×				75/36 - JUN 2001	PASTO	MARIAN
	(HUMIDITY) SAMPLE #3	1.67	×				75/35 - JUN 2001	PASTO	MARKA
	AVERAGE HUMIDITY	2 5	×				7586 - JUN 2001	PASTO	MARMA



Analyses Report

Laboratory Information Management System

Pharmaceutical Development

Sample ID (Request No.) ; 20011710

User sample ID (lot) : **IBAGICZ** Sample Typer StU010366 (PNU280840AD) CAPSULE 50 MG

Samples Notes:

Stability Study: 183G02

Condition:

Pack Typic BULK	Shorage Conditions, TIME ZERO	Time Labor, TME ZERO	Preparation purpose: STABILITY

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Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Book-Data Analyses	Analyst	Verifier
DESCRIPCINGO SAMPLE#1	SAMPLE #1	97.A	*		- 00098	115,000	7586 - JUN 2001	PASTO	INSPAN
-	SAMPLE #2	101.2	₩.		96.000 -	115,000	7585 - JUN 2001	PASTO	MARIAN
	SAMPLE #3	101.3	×		85,000 -	115.000	75.085 - JUN 200M	PASTO	MARIAN
	SAMPLE #4	100.3	×		- 92,000	115.000	75/35 - JUN 2001	PASTO	KARIMA
	SAMPLE#5	1022	¥		85,000 -	- 115.000	75/35 - JUN 2001	PASTO	KARIAN
	SAMPLE #6	58.2	×		85.000	115,000	75/36 - JUN 2001	PASTO	MARKAN
	SAMPLE #7	98.4	¥		96,000	115,000	7585 - AM 2001	PASTO	MARIAM
	SAMPLE #8	97.2	×		96,000	115.000	75/35-JUN 2001	PASTO	MARIAN
	SAMPLE #9	8.55	×		B\$5,000	115.000	75/55 - JUN 2001	PASTO	MARAN
	SAMPLE #10	105.8	*		98,000	115,000	75/36 - JUN 2001	PASTO	MARIAN
	SAMPLE #11	87.3	×		BECO00 -	115,000	75/35 - JUN 2001	PASTO	MAKHAM
	SAMPLE #12	87.3	×		96.000	115.000	75/35 - JUN 2001	PASTD	MARIAN
	SAMPLE #13	2,84	*		. 000'S	115,000	7485 - JUN 2001	PASTO	MARKAN
	SAMPLE #14	100,7	*		- 000'58	115.000	75/35 - JUN 2001	PASTO	MARIAN
	SAMPLE #15	992	×		- 00079	115,000	75/35 - JUN 2001	PASTO	MARKAN
	SAMPLE #16	. 96.7	×		95,000	115,000	75/25 - JUN 2001	PASTO	MARKANI
	· SAMPLE #17	95.8	×		. 000'59	115.000	75/96 - JUN 2001	PASTO	MARKAN
	· SAMPLE#18	8.68	Ŋ		. 000799	115.000	75/35-JUN 2001	PASTO	MARIAM
	I SAMPLE #19	96.3	×		- 00038	115,000	7505 - JUN 2001	PASTO	MARIAM
	· SAMPLE #20	87.5	×					PASTO	



Analyses Report

Laboratory Information Management System

Pharmaceutical Development

Saturierion Id: 119761
Sample ID (Request No.) ; 2001(71)
User sample ID (lot) ; 19902(12
Sample Type: Stofosee (FINIZEDS GAPSULE 50
MS

Similarly Study: ISSG02
Pack Type: BULK
Storage Condition: TillE-723(0
Thes Label: TIME 723(0
Preparation purpose: STABILITY

COMPLETE

Method Controls 083GUPO1#0 SAMPLE 1 AVERAGE STANDAI	ols		M.U.	The same of the last		THE PERSON NAMED IN COLUMN	***************************************	The latest and the same of the same of	Designation of the Publisher of the Publisher.
GGSGUPONO SAMPLE#20 1 AVERAGE WI STANDARD I		Kesuits		Spec7	Lower lim	Upper lim	Lower im Upper lim Book-Data Analyses	Analyst	Verifier
AVER&	LE #20	87.6	*		85.000	115,000	7526 - JUN 2001		MARIAN
STANE	AVERAGE WEIGHT	98.61	×		- 00039	- 115,000	75/85-JUN 2011	PASTO	LAHAM
	STANDARD DEVIATION	2.822	ģ				75/35 - JUN 2001	PASTO	MARIAN
C.V.		2.95	*				75/35 - JUN 2001	PASTO	MARIAN
MINIM	MINIMUM VALUE	85.5	×		95.000	- 115,000	75/85 - JUN 2001	PASTO	MARAN
MAXIN	MAXIMUM VALUE	105.6	×	•	85,000	115,000	75/85 - JUN 2001	PASTO	NATION.
083GDS51#0 1_12									
DESCRICOTED TOTAL	DESCRIPCION TOTAL AEROBIC BACTERIA	INLINITS	z				SYOLAB MAY 2001	PASTO	MARIAN
T ESCHE	ESCHERICHIA COLI	ABSENT	E				BIOLAB MAY 2001	PASTO	MARIAM
SALM	SALMONELLA	ABSENT	ĕ				BIOLAB MAY 2001	PASTO	MARKIN
FUNGI	_	RY LAMITS	¥				BICILAB MAY 2001	PASTO	MARKA
STAPH	STAPHYLOCOCCUS AUREUS	ABSENT	X				BIOLAB NAV 2001	PASTO	MARKAN
ENTER	ENTEROBACTERIA	ABSENT	B				BIOLAS MAY 2001	PASTO	MAHAM



Loborotory Enformation Management System

Pharmacia & Upjohn Pharmaceutical Development

Sample ID (Request No.) : 2001171

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Samples Notes:

Stability Study; 1936:02
Pack Type: BULK
Stange Centilion: TME ZERO
The Label: TME ZERO

APPROVED Status: COMPLETE

IBBGRIZ SUPICE	Die ID (Kequest No.) : 20111718 User sample ID (lot) : 163C412 Beantle Twee: SUD10368		SUDJESSE (PHELSSES AGAIL) CAPSULE 50
		2005E	SUCHESOR

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Method Controls	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Lower lim Upper IIm Book-Data Analyses	Analyst	Verifier
COSCOSOTIO SAMPLE#1	SAMPLE#1	37.75	×		30,000		75755-JUN 2001	PASTO	MAHAM
<u>-</u>	SAMPLE #2	100.5	×		\$0.000		75/86 - J.IN 2001	PASTO	MARKAN
	SAMPLE #3	0.00	ył.	,	000700		75/26 - JUN 2001	PASTO	MARIAN
	SAMPLE #4	95.5	zł.		90,000		75/35 - JUN 2001	PASTO	MARIANI
	SAMPLE #5	6.63	**		80.000		75856 JUN 2001	PASTO	MARIBANI
	SAMPLE #6	97.2	at		80,000		75/35 - JUN 2001	PASTO	MARKANI
	SAMPLE #7	58.7	*		\$0.000		75/36 - JUN 2001	PASTO	MARIANI
	SAMPLE #8	8.08	3 %		80.000		75/35 - JUN 2001	PASTO	MAKINAM
	SAMPLE #9	87.8	×		90,000		75X15 - JUN 2001	PASTO	MARIMA
	SAMPLE #10	7.96	*		B0.000		75/26 - JUN 2001	PASTO	MARIAM
	SAMPLE #11	Q OS	*		80,000		75/35 - JUN 2001	PASTO	MARIAN
	SAMPLE #12	98.0	×		90,000		75/35 - JUN 2001	PASTO	MARAN
	DISSOLUTION	98.51	*		80,000		75/85 - JUN 2007	PASTO	MARKAN
	STANDARD DEVIATION	1.335	費				7676 - JUN 2006	PASTO	INAPKANI
	C.V.	1.36	×				75/25 - JUN 2001	PASTO	MARIAN
	MIN. DISSOLUTION VALUE	85.5	¥		80.000		75/36 - JUN 2001	PASTO	MARIAM
	MAX. DISSOLUTION VALUE	100.5	*	•	80.000		75/05 - JUN 2001	PASTO	MAPAN

Monagement Information aboratory System

Sample ID (Request No.) : 20011710 Submission id: 113751

Sample Type: SU010398 (PNU290940AD) CAPSULE 50 User sample ID (lot) : 185502

Strags Condition: TMEZERO Statisticy Study; INSIGIZ Pack Type: BULK

Time Label: TME ZENO Preparation purpose: STABILITY

Condition: APPROVED

COMPLETE

Samples Notes:

083GC001#01, component: APPEARANCE **Observations** on the Method Opaque brick red colored shaped hard gelatin capsule containing yellow-orange colored powder

Observations on the Method 083GDS01#01_12, component: MAXIMUM DISSOLUTION VALUE

no comment

083GDS01#01_12, component: DISSOLUTION Observations on the Method

Average dissolution at 15 minutes: 97.7% (C.V. 2.6%) Average dissolution at 30 minutes: 96.5% (C.V. 1.4%) Average dissolution at 45 minutes: 99.5% (C.V. 1.7%)

083GMC01#01, component: TOTAL AEROBIC BACTERIA Observations on the Method

Total bacteria count < 10 Ufc/g (Report No. 01.1231)

Observations on the Method 083GMC01#01, component: ENTEROBACTERIA

Enterobacteria < 10 Ufc/g (Report No. 01.1231)

Observations on the Method 083GMC01#01, component: ESCHERICHIA COLI

Test dane on 10g (Report No. 01.1231)

083GMC01#01, component: FUNGI Observations on the Method

Fungi (yeasts and molds) < 10 Ufc/g (Report No. 01.1231)

Observations on the Method 083GMC01#01, component: SALMONELLA

Test done on 10g (Report No. 01.1231)

083GMC01#01, component: STAPHYLOCOCCUS AUREUS Observations on the Method

Report No. 01.1231

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05% Observations on the Method

correlated substances RRT 0.690 (Impurities A): 0.16%

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Monagement System Information Laboratory

Semple Type: SUDJOSOS (PRU250840AD) CAPSULE SO NG

#ubmtselon)d; 113751 Sample ID (Request No.) :: 20011710 User sample ID (lot) : [83G62

Statually Study: ASSOC

Slorage Cendifion: TIME ZERO Pack Type: BULK

Time Labet TIME ZERO Preparation purpose: STABILITY

CONCEPTED APPROVED

COMPLETE Steller:

Samples Notes:

Observations on the Method 083GC01#00, component: IMPURITIES NOT LESS THAN 0.05%

RMT 0.026 (MPURITIES. B): 0.04 %
RMT 1.069 (MPURITIES D): 0.15 %
RMT 1.069 (MPURITIES D): 0.25 %
RMT 1.069 (MPURITIES E): 0.11 %

PAST 1.142 (IMPURITIES F): 0.07%

RAT 1.281 (IMPURITIES 14): 0.15 % RAT 1.272 (IMPURITIES 14): 0.15 % RAT 1.646 (IMPURITIES 1): 0.16 %

rvations on the Method 083GUP01#01, component: AVERAGE WEIGHT The average weight is equal to 98.61% which corresponds to 87.85 mg per capsule. Observations on the Method

Approved by: MARIANI Approval date: 13-jun-2001

Integrated Analytical Bulletin

Edboratory Information Management System

Pharmaceutical Development

Sample ID (Request No.) : 20012048 Submiterion ich 113992

Sample Date: 30/08/2001 User sample ID (lot) : \$35602

Sample Typer SU010346 (PARIZSOB40AD) GAPSULE 50

Stability Study Start Date S.P.N. 2001D05 - Manufacturer (ASP375-MTM-0002 Samples Notes:

Pask Type: 30 ml PLASTIC BOTTLE Sterage Coudition: 25/080% U.R. Time Label: 1 MONTH

Better Manufacture Date: 17/05/2001

Stability Study: 185002

APPROVED SOMPLETE

Preparation purpose: \$TABILITY			
PAG .	mte.: \$1/05/2001	HER POPPIARMACIA NIRVIGIO - API BIRCH	

Management of the Parket.	CARLES AND	Management and other Designations of the least of the lea	-	CALCONOLABIA SOCIAL	PRINCIPAL DESCRIPTION	**************************************	CANADA STREET,		CHARLES
Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Lower lim Upper lim Book-Data Analyses	Analyst	Verifier
OKEIGEDOOZNO	OKSIGNOCZIO CAPSULE APPEARANCE	0=UNCHANGED	· 3				15441/01 - AUB 2001	COLOMBOD	MARIAN
	CAPSULE COLOR	0=UNCHANGED	Ħ				15441/61 - AUR 2001	COLOMBOD	MARIAM
	CONTENT APPEARANCE	0=UNCHANGED	Ħ				1544kM - AUG 2001	COMMODU	MARIAM
	CONTENT COLOR	0=UNCHANGED	Ħ				15441701 - AUG 2001	CORNOTOS	MARINA
	SMELL	0=UNCHANGED	Ħ				1544101 - AUG 2001	COLOMBOD	MARIAN
083GTD(#01	OSSCTIDIMOT (HPLC TITER) SAMPLE#1	*	*		90,000	110,000	1644 s02 - AUG 2001	COCCURBOD	MARIAN
4	(HPLC TITER) SAMPLE#2	1.50	*		9a.too -	110,000	15H1M2 - AUG 2001	CONTON	MARIAN
	(HPLC TITER) SAMPLE#3	0'96	*		90.000	110.000	15441/02 - AUG-2001	COLCUBOD	MARIAN
	AVERAGE TITER (HPLC)	98.17	¥		90.000	110.000	15441/02 - AUG 2001	COLOMBOD	MARIAN
0836550180	OSSCICOTAL CORRELATED SUBSTANCES	104	¥ŧ				1544705 - AUB 2001	COLCUMBOD	MAHAN
>	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	×				1544170s - AUG 2001 .	COLUMBOD	MARKAN
DESCRICTON WOOD	OBSOMED1#00 (HUMIDITY) SAMPLE#1	20	×				15441708 - AUG 2001	COLDMBOD	MAPKARU
	(HUMIDITY) SAMPLE #2	20	×				1544109 - AUG 2001	COLCALIBOD	MARKAN
	(HUMIDITY) SAMPLE #3	2.0	×				15441/03 - AUG 2001	COLOMBOD	MARKA
	AVERAGE HUMIDITY	4	¥				15441/03 - AUG 2001	CONTON	MARKAN

Pharmaceutical Development

Integrated Analytical Bulletin

kabaratay Information Management System

> Sample ID (Request No.) ; 20012048 Submibeloniid: 119992

User sample ID (lot) : 1835,02

Semple Date: 30/06/2001

Sample Type: SU010398 (PNUZB0940AD) CAPRULEISO

PackTyper 30 ml PLASTIC BOTTLE Shorage Candillone 25/CR0% U.B. Time Label: 1 MONTH Stability Study: ISSO02

Butch Manufactors Date: 17/05/2001

Preparation purpose: STABILITY

Condition: APPROVED Sentur: COMPLETE

Shibling Shudy Start Dalle : 31705/2001

S.P.N. 2001005 - Merulinchurer POAP! MEMARCIA Nervieno - API Batch (NSS75-MTM-0002

Samples Notes:

Method	Controls	Results	M.U.	Spec?	Lower lim U	pper lim	Lower lim Upper lim Book-Data Analyses	Analyst	Verifier
OBSCIDEDAND	SAMPLE#1	101.4	×		90,000	,	15441/4 SEP 2001	PASTO	MARIAN
	SAMPLE#2	432	×		80,000		154414867-2001	PASTO	MANIAN
	SAMPLE#3	£00.8	¥		000'00		154414 SEP 2001	PASTO	MARIAN
	SAMPLE#4	7,98	×		900:00		15441/4 SEP 2001	PASTO	HARAM
	SAMPLE#5	198.7	36		90,000		(644)/4 SEP 2001	PASTO	MARKAN
	SAMPLE#6	87.9	*		40,000		154414 SEP 2001	PASTO	HAPPAN
	DISSOLUTION	100.97	38		30,000		1541/4 SEP 2001	PASTO	ICATION
	STANDARD DEVIATION	1,789	14				15441/4 SEP 2001	PASTO	MARRAM
	C.V.	1.78	×				154414 SEP 2001	PASTO	MARKAN
	MIN. DISSOLUTION VALUE	87.8	¥		80.000		ISAKIM SEP 2001	PASTO	MARIANI
	MAX. DISSOLUTION VALUE	103.2	¥		000'08		1544144 SEP 2001	PASTO	MARIAN



Pharmaceutical Development

Integrated Analytical Bulletin

Management information Laboratory System

APPROVED

Statue: COMPLETE

Pack Type: 30 ml PLASTIC BOTTLE

Baich Manufacture Date: 1785/2001 State May Shedy: 185G02 Stange Condition: 25°C/60% U.A. Time Later: 1 MONTH
Preparation purpose: STABILITY

Submission id: 113992

Sample ID (Request No.) : 20012049

User sample ID (lot) : [83G02

Semple Date : 30/06/2001

Sumple Type: Such page (PRN250G-PAD) CAPSULESD MG

S.P.N. 2001005 - Manufacturar POPPHARMACIA Meritano - API Beich

Beatifig Shady Mert Date: 31/05/2001

CASSATTM-CODE Samples Notes:

083GDS01#01, component: DISSOLUTION Observations on the Method

average dissolution per single capsule after 15 minutes: 96.5% (C.V. 2.0%)

average dissolution per single capsule after 30 minutes: 100.4% (C.V. 1.3%) average dissolution per single capsule after 45 minutes: 100.7% (C.V. 2.0%)

Observations on the Method

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

CORRELATED SUBSTANCES RAT QUET: Q.09%

PRT 0.915: 0.05% PHT 0.828 : 0.11%

RFT 1.054:0.29%

ART 1.084: 0.09%

PHT 1.257:0.09% PHT 1.267:0.19% PHT 1.845:0.13%

Approved by: MANHANI
Approval date: 07-esp-2021

by MARIAN

07~SEP-2001 01:58 PM Printed

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Pharmaceutical Development

Integrated Analytical Bulletin

Information
Management
System Laboratory

Submission it: 113894

Sample ID (Request No.) ¢ 20012051 User sample ID (lot) | BOGU2 Semple Dete: 3006/2001

Semple Type: SUD10368 (PNU290840AD) CAPSULE 50 MRG MRG

Plack Type: 30 ml PLASTIC BOTTLE Showing Courtibles: 40×075% U.R. Baick Manufacture Date: 17/05/2001 Shahility Stady: 183G02.

Time Labol: 1 12CNT3
Preparation purpose: STABILITY

APPROVED

SHAME: COMPLETE

Stability Study React Date: 31/05/2001

Samples Notes:

S.P.N. 2001006 - Manufestum PDIPHMRARCA Nerdano - API Bath (Aperts ATM-0002

-	CCAMEDIAL MENT PROPERTY OF THE	AND THE PROPERTY OF THE PERSONS			AND THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED IN COLUMN TWO IS NAMED IN			
Method	Controls	Results.	M.	Spec?	Lower lim Upper lim	Book-Data Analyses	Analyst	Veriffer
OHZOCICSEBO	089GDOOMO CAPSULE APPEARANCE	0=ÙNCHANGED	Ħ			1544102 - AUG 2001	COLCURSOD	MARIAN
0	CAPSULE COLOR	0=UNCHANGED	Ħ			1544102 - AUG 2001	COLOMBOD	MARKAN
	CONTENT APPEARANCE	0=UNCHANGED	Ħ			15441/02 - AUG 2001	CONTRIBUD	MASIAN
	CONTENT COLOR	0=UNCHANGED	幫			15441/02 - AUG 2001	COLCUBOD	MANAM
	SMELL	0=UNCHANGED	Ħ			1544172 - AUG 2001	COLOMBOD	MARIAN
ORCHITICA MOT	ORSCITICIAN (HPLC TITER) SAMPLE#1	87.8	×		90.000 - 110.000	15441702 - AUG 2001	COLCAMBOD	MACHAIN
m,	(HPLC TITER) SAMPLE#2	86.7	×		90,000 - 110,000	15441A2 - AUG 2001	COLOMBOD	MARIAM
	(HPLC TITER) SAMPLE#3	98.1	*		90,000 - 110,000	15441/02 - AUG 2001	COLCHEOD	MARKAN
	AVERAGE TITER (HPLC)	15.19	×		90.000 - 110,000	15441/02 - AUG 2001	COLOMBOD	MARKIN
OBSGSCO1#0	003GSC01#0 TOTAL CORRELATED SUBSTANCES	121	*			1544103 - AUG 2001	COLOMBOD	MARKAI
=	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	×			1544103 - AUS 2001	COLOMBOD	MARIANI
ORDERGROTARO	ORDERGROS (HUMIDITY) SAMPLE #1	1.9	*			15441Ats - AUG 2001	COLOMBOD	HAPAAN
	(HUMIDITY) SAMPLE #2	21	¥			15441,000 - AUG 2001	COLONBOD	MARKAN
	(HUMIDITY) SAMPLE #3	2.0	*			15441/03 - AUG 2001	COCOMBOD	MARIAN
	AVERAGE HUMIDITY	N	×			1544108 - AUS 2001	COLUMBOD	MARKE.



Integrated Analytical Bulletin

Monagement System Loboratory Information

Sample ID (Request No.) 3 20012051 Sobolisation lit: 1(3894

Sample Date: 30/06/2001 User sample ID (lot) : 183/602

Semple Types SUG(0398 (PNL)290940AD) CAPSULE SO RM3

Butch Manafacture Date: 17/05/2001 Stability Staty: 183802

Pack Type: 30 ml PLASTIC BOTTLE Sterage Condition 40/C/75% U.R.

Time Labut: 1 AIONTH Preparation purpose: STABILITY

CONDITION: APPROVED

COMPLETE

Stability Starty Start Date: 31/05/2001

Samples Notes:

S.P.N. 2001005 - Manufacturer PD/PHARMACIA Netwiggs - APT Back (NSWTS-MTM-0002

Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Lower im Upper im Book-Data Analyses	Analyst	Verifier
DESGDSOTIO	SAMPLE#1	8796	ĸ		80,000		1541/4 SEP 2001	PASTO	MARKAN
	SAMPLE#2	7.98	×		90,000		15441/4 SEP 2001	PASTO	MARKA
	SAMPLE#3	0'86	×		80.000		154414 SEP 2001	PASTO	MARKAN
	SAMPLE#4	8	3 8		90,000		15441# SEP 2001	PASTO	MARRAN
	SAMPLE #5	95.2	×		90,000		154414 SEP 2001	PASTO	MAHAN
	SAMPLE #6	37.5	*		80,000		15441/4 SEP 2001	PASTO	MARIAN
	DISSOLUTION	97.2	¥		90,000		154¢1/4 SEP 2001	PASTO	MARKAN
	STANDARD DEVIATION	1,685	£				154414 SEP 2001	PASTO	MARKAN
	C.V.	1.63	æ				1544/4 SEP 2001	PASTO	MARIAN
	MIN. DISSOLUTION VALUE	95.2	¥		000'09		1544M BEP 2001	PASTO	HAFHAM
	MAX. DISSOLUTION VALUE	0'8'8	*		90,000		154414 SEP 2001	PASTO	HARRAN



Pharmacia & Upjohn
Pharmaceutical Development

Integrated Analytical Bulletin

Monagement Information Laboratory System

Schmitschow its 119994

Sample ID (Request No.) : 20012051 User sample ID (lot) c 189602 Berriple Date : 30/05/2201

Demote Type: S1010389 (PNU280HOAD) CAPSULE 50

Statch Manufacture Date: 17/05/2004

Pack Types 30 ml PLASTIC BOTTLE Storage Condition; 40/C/76% U.R. State Study: 163002.

Time Letet: 1 MONTH
Preparation purpose: STABILITY

CONDENS APPROVED Settor: COMPLETE

SMADINES SHeady Short Dathe : STACK2001 S.P.A. 2001005 - Minuskadurer PDJPS-AGNACIA Nervieno - API Belch (A)SR7S-MITM-0002

Samples Notes:

083GDS01#01, component: DISSOLUTION average dissolution per single capsule after 15 minutes: 98.0% (CV 1.5%) average dissolution per single capsule after 30 minutes: 97.2% (CV 1.6%) Observations on the Method

average dissolution per single capsule after 45 minutes: 97.3% (CV 1.6%)

Observations on the Method 083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05%

CORRELATED SUBSTANCES FRIT 0.091; 0.00%

ART 0.916: 0,00% PART 0.028; 0.13%

PAST C.DSG: C.CSX

RHT 1,064: 0.34% RRT 1.008:0.16%

RHT 1.270: 0.15% HRT 1.260; 0,08%

PRIT 1455: 0.14%

Approved by: MARIANI Approval date: 07-ssp-2001

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Information Management System Laboratory

Pharmaceutical Development

Submission 1d: 115782 Sample ID (Request No.) ; 20020525 User sample ID (lot) ; 183G02 Sample Type: SU010398 (PNUZB0940AD) CAPSULE 50 MG

Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 25/C/50% U.R. Time Labet: 9 MONTHS Preparation purpose: STABILITY Request Type: RELEASE Stability Study: 183G02

Condition: APPROVED

Status: COMPLETE

Samples Notes									
Method	Controls	Results	M.U.	Spec?	Lower lim	Lower lim Upper lim	Book-Data Analyses	Analyst Ve	Verifier
)83GCO02#0	083GCO02#0 , CAPSULE APPEARANCE	CONFORMS	Ħ				15545/08- MAR 2002	CAPFUCCIO	MARIANI
_	, CAPSULE COLOR	CONFORMS	ቖ				15545/08- MAR 2002	CAPPUCCIO	MARIANI
-	· CONTENT APPEARANCE	CONFORMS	¥				15545/08- MAR 2002	CAPPUCCIO	MARIANI
	CONTENT COLOR	CONFORMS	Ħ				15545/08- MAR 2002	CAPPUCCIO	MARIANI
	· SMELL	CONFORMS	¥				15545/08- MAR 2002	CAPPUCCIO	MARIANI
83GTI01#01_	083GTI01#01 (HPLC TITER) SAMPLE#1	100.2	%		90,000	- 110,000	15545/08- MAR 2002	CAPPUCCIO	MARIANI
	(HPLC TITER) SAMPLE#2	99.5	26		90,000	- 110,000	15545/08- WAR 2002	CAPPUCCIO	MARIANI
	· (HPLC TITER) SAMPLE#3	99.4	*		90.000	- 110.000	15545/08- MAR 2002	CAPPUCCIO	MARIANI
	' AVERAGE TITER (HPLC)	200.7	*		90:000	- 110.000	15545/08- MAR 2002	CAPPUCCIO	MARIANI
83GSC01#00	083GSC01#00 · TOTAL CORRELATED SUBSTANCES	0.81	*				15545/08- MAR 2002	CAPPUCCIO	MARIAN
	· IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	*				15545/08- WAR 2002	CAPPUCCIO	MARIAN
33GKF01#00	083GKF01#00 · (HUMIDITY) SAMPLE #1	2.2	%	/5	926.28		15545/08- MAR 2002	CAPPUCCIO	MARIANI
	· (HUMIDITY) SAMPLE #2	2.1	%	es.		B	15545/08- MAR 2002	CAPPUCCIO	MARIAN
_	, (HUMIDITY) SAMPLE #3	2.2	%	02	"	32	15545/08- MAR 2002	CAPPUCCIO	MARIANI
	I AVERAGE HUMIDITY.	2.17	%	ัน ใน	Received	3031	15545/08- MAR 2002	CAPPUCCIO	MARIANI
				91.21.71.	919141	-123			
					6789701	20			

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Information Management System Laboratory

Pharmaceutical Development

Submission (d; 115782 Sample ID (Request No.); 20020525 User sample ID (lot): 183G02

Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 25°C/60% U.R. Request Type: RELEASE Stability Study: 183G02

Condition: APPROVED

Status:

	Sample Type: SU010398 (PNU290940AD) CAPSULE 50 MG	90940AD) CAPSULE 50		Preparatic	Time Label: 9 MONTHS Preparation purpose: STABILITY	9 MONTHS STABILITY	4	COMPLETE	ш
Samples Notes:	mornow mate were entered of the transmission of the property o	Last all the state of the second					ساب خسسهار سپونید دادان سینسیان، یاضای آزار هستهای دول شدا یام هستهای دول شدار شد		
Method	Controls	Results	M.U.	Spec?	Lower lim	Upper lim	Lower lim Upper lim Book-Data Analyses	Analyst	Verifie
083GDS01#01 SAMPLE#1	SAMPLE #1	97.15	*		80,000		15545/08- MAR 2002	CAPPUCCIO	
	SAMPLE #2	98.05	*		80,000		15545/08- MAR 2002	CAPPUCCIO	
	SAMPLE #3	99.61	\$8		80,000	•	15545/08- MAR 2002	CAPPUCCIO	
	SAMPLE #4	100.49	*		80.000		15545/08- MAR 2002	CAPPUCCIO	
•	SAMPLE #5	99.57	*		80.000		15545/08- MAR 2002	CAPPUCCIO	
-	SAMPLE #6	100.12	×		60,000		15545/08- MAR 2002	CAPPUCCIO	
	DISSOLUTION	99.17	×		80,000		15545/08- MAR 2002	CAPPUCCIO	
	STANDARD DEVIATION	1,291	std-1				15545/08- MAR 2002	CAPPUCCIO	-
	C.V.	1.3	%				15545/08- MAR 2002	CAPPLICCIO	
	MIN. DISSOLUTION VALUE	97.15	æ		80,000		15545/08- MAR 2002	CAPPUCCIO	
	MAX. DISSOLUTION VALUE	100.49	%		80.000		15545/08- MAR 2002	CAPPUCCIO	

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Management System Information Laboratory

. Pharmaceutical Development

Sample ID (Request No.): 20020525 User sample ID (lot) : 183G02 Submission id: 115762

Sample Type: SU010398 (PNU290940AD) CAPSULE 50

Request Type: RELEASE Stability Study: 183G02

Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 25/C/80% U.R. Time Label: 9 MONTHS Preparation purpose: STABILITY

Condition: APPROVED

Status: COMPLETE

Samples Notes:

083GCO02#00, component: CAPSULE APPEARANCE Observations on the Method

Opaque brick red colored hard gelatin capsute containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION The dissolution values were corrected based on the weight of the respective capsule

Average dissolution at 15 minutes: (interval 96.4% - 100.1%) Average dissolution at 45 minutes: (interval 98.6% - 100.2%)

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05% Observations on the Method

Total correlated substances: 0.81%

Area % 쭚

0.89

0.12 99.19 0.20 0.10

(SU 11248)

0.07

25-mar-2002 MARIAN Approved by: Approval date:

-es



Pharmaceutical Development

Monogement System Laboratory Information

Integrated Analytical Bulletin

Sample ID (Request No.): 20013447 Pubrulesion id: 115149

User sample ID (lot)c ISEGUZ

Marpho Date : 30/11/2001

Security Types SUO10898 (PNU290940AD) CAPBULE 50 MG

Batick Manadacture Date: 17/05/2001 Machiney Study: 850022

Pock Types 30 ml PLASTIC BOTTLE Storage Condition: 257C/80% U.P. Time Labet: & MONTHS

Preparation purpose: STABILITY

APPROVED

COMPLETE

S.P.N. 2001005 - Mandedurar FD/FHARMACIA Merulmo - API Balch (A)5975-MTM-0002 Stubility Shady Start Date : 31/05/2001

BACCAPI MACCARI MACCARI MACCARI MACCAR MACCARI MACCAR MACCABI MACCARI MACCAR MACCARI MACCAPA EACCAN MACCAN MCCAR **MACCARI** Verifier CAPPUCCIO CAPPUCCIO CAPPUCCIO CAPPUDGED CAPPUCCIO CAPPUCCIO CAPPLICCIO CAPPLICCIO CAPPLYCCIO CAPPUCCIO CAPPLICCED CAPPUCCO CAPPUCCIO CAPPLICATE CAPPUCCED Analyst Spec? Lower lim Upper lim Book-Data Analyses 143/27 DEC 2001 (48/27 DEC 2001 (49/27 DEC 2001 MOUNT DEC 2001 14S/Z7 DEC 2001 KAZZ DEC 2001 143,627 DEC 2001 (45/27 DEC 2001 143/27 DEC 2001 143tz7 DEC 2001 43/27 DEC 2001 14SZ7 DEC 2001 143/27 DEC 2001 1454ZZZ DEC 2001 ASYZY DEC 2007 90,000 - 110,000 90,000 - 110,000 90.000 - 170.000 S0.030 - 110,000 M.U. CONFORMS CONFORMS CONFORMS CONFORMS CONFORMS IMPURITIES NOT LESS THAN 0.05% SEE TEXT Results 28,57 86,30 99.85 1.73 2 DESCRIPTION TOTAL CORRELATED SUBSTANCES 0.9 1,7 CONTENT APPEARANCE DESGOCIATO CAPSULE APPEARANCE OBSOTION (HPLC TITER) SAMPLE#1 (HPLC TITER) SAMPLE#2 (HPLC TITER) SAMPLE#3 AVERAGE TITER (HPLC) DESCRIPTION (HUMIDITY) SAMPLE #1 (HUMIDITY) SAMPLE #3 (HUMIDITY) SAMPLE #2 AVERAGE HUMIDITY CONTENT COLOR CAPSULE COLOR Controls SMELL Samples Notes: Method

by MACCAR Printed 11-DEC-2001 10:28 AM



Pharmaceutical Development

Integrated Analytical Builetin

Monogement System Laboratory Information

> Sample ID (Request No.) 20013477 User sample ID (lot) 183C92 Submittelen idt 115149

Shemple Date : 3071172001 Shemple Type: 5U010006 (PRV2x004(AAD) CAPBULE 50 INB

Prick Types 30 ml PLASTIC BOTTLE Storage Conflices 25/C60% U.R. The Labet GACNTHB
Preparation purpose: STABILITY Sinkling Study: 1600002

Batch Menuferture Date: 17/05/2001

Condition: APPROVED

SHAME: COMPLETE

S.P.N. 2001005 - Manufacturer PO/PHARMACIA Navieno - API Batch (A)8979-MITH-0002

Samples Notes:	otes:							ē
Method	Method Controls	Results	M.U.	Spec?	Lower lim Upper lim	M.U. Spec? Lower lim Upper lim Book-Data Analyses	Analyst	Verifier
**************************************	083GDSC1#0 SAMPLE #1	67.9	¥		80,000	149/27 DEC 2001	CAPPUCCIO	MACCARI
	SAMPLE #2	100.2	*		80.500	HS27 DEC 2001	CAPPUCCIO	MACCAPI
	SAMPLE #3	47.4	×		80.500	143/Z7 DBC 2301	CAPPLICOLO	MACCARI
	SAMPLE #4	886.8	×		30,000	149Z7 DEC 2001	CAPPICCIO	MACCARI
	SAMPLE #5	102.7	ył.		90,000	14327 DEC 2001	CAPPUOCIO	HOCCAR
	SAMPLE #6	100.2	¥		80.000	14927 DEC 2001	CAPPUCCIO	_
	DISSOLUTION	23,00	¥		80,500	145/27 DEC 2001	CAPPUCCIO	MACCAPA
	STANDARD DEVIATION	1.833	<u>-</u>			143Z7 DEC 2001	CAPPUCCIO	MACCAPI
	C.V.	7.	*			14327 DBC 2001	CAPPUCCIO	HACCAFE
	MIN. DISSOLUTION VALUE	97,36	*		90.000	14327 DEC 200(CAPPUCCIO	MACCARI
	MAX. DISSOLUTION VALUE	1 22.7	*		B0.000	14927 DEC 2001	CAPPUCCIO	MACCAPI

Integrated Analytical Bulletin

Information Management System Loboratory

Schralesien it: 115149

Sample ID (Request No.): 20013447

Bempie Date : 90/11/2001 User sample ID (lot): 163/G02

Simple Type: Stotoxes (PNU290940AD) CAPSULETO

Bailch Manufacture Date: 17/05/2001 Shelpliky Study: (83002

Fack Type: 30 ml PLASTIC BOTTLE

Months Condition: 25'CAUX U.R. Time Labit: 6 MONTHS
Preparation purpose: STABILITY

CONTROL : APPROVED

States: COMPLETE

Stability Stady Start Date: 31/05/2001

S.P.H. 200 totis - Manufacturer PORP! MYBLACIA Narvieno - APT BADTI. (Ajsans-Antial-Ogoz.

Samples Notes:

083GC002#00, component: CAPSULE APPEARANCE Observations on the Method

Opaque brick red colored hard gelatin capsule containing yellow-orange powder

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05% Observations on the Method

Total correlated substances: 0.9%

ATE X 뚪

600 0.0056 0.90 0.90 0.91

0.110 98.096 0.124

0.136 0.170 0.173 0.184

MACCAFI 11-dec-2031 Approved by: Approval date:

Integrated Analytical Bulletin

Eclopation Information Management System

Sample ID (Request No.) : 20013449

User sample ID (tot) : 184(562

Statuthey Study: 183/902
PackType: 30 ml PLASTIC BOTTLE
Storage Condition: 40/075% U.H.

Belok Manufacture Date: 17/05/2001

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STATE
COMPINED
COMPINED

Charles Date: 30/1/2301	TIME SUNATHS	
Spanjain Type: Storiospa (PNU280940AD) GAPSULE 50 MG	Preparation purpose: STABILITY	
Stability Staby Start Bate: St/05/2001		
S.P.N. 2004005 - Manufachurer PDAPHAPHAACIA Narvieno - API Batch		
(A)S975-MTM-coure		
Samoles Notes:		

Method	Controls	Results	M.U.	Spec?	Lower lim Upper lim	Book-Data Analyses	Analyst	Verifier	þ
1300001	0839CC0240 CAPSULE APPEARANCE	CONFORMS	Ħ			44527 DEG 2001	83	CAPPUCCIO	MACCAR
	CAPSULE COLOR	CONFORMS	Ħ			149/27 DEC 2001	d CAP	CAPPUCCIO	MACCARI
	CONTENT APPEARANCE	CONFORMS	Ħ			149/Z7 DEC 2001	a¥3	CAPPUCCIO	MACCAR
	CONTENT COLOR	CONFORMS	Ħ			143/Z7 DEC 2001	3	CAPPUCCHO	MACCARE
	SMELL	CONFORMS	Ħ			14527 DEC 2001	8	CAPPUCCIO	MACCARI
BESTIDIA	O69CTID1#01 (HPLC TITER) SAMPLE#1	96.57	æ		90,000 - 110,000	0 14927 DEC 2001	35	CAPPUCCIO	MACCARE
4 0.	(HPLC TITER) SAMPLE#2	75.89	×		90,000 - 110,000	0 143/27 DEC 2001	CAP	CAPPUCCIO	MACCAR
	(HPLC TITER) SAMPLE#3	100.00	×		90,000 - 110,000	30 149/27 DEC 2001	av S	CAPPUCCIO	MACCAR
	AVERAGE TITER (HPLC)	99.41	×		90,000 - 110,000	00 149Z7 DEC 2001	20	CAPPUNCIO	MACCARI
BGSC014	OBSISSION TOTAL CORRELATED SUBSTANCES	75.0	×			14S/Z7 DEC 2001	3	CAPPUCCIO	MACCAR
	IMPURITIES NOT LESS THAN 0.05%	SEE TEXT	R			143/Z7 DEC 2001	8	CAPPLICCIO	MACCAR
ESCACEDIN	DBSCACEDINOG(HUMIDITY) SAMPLE #1	22	ĸ			143/27 DEC 2001	3	CAPPLICCIO	MACCAR
	· (HUMIDITY) SAMPLE #2	2	¥			143/Z7 DEC 2001	8	CAPPUCCHO	HMOCAR
	(HUMIDITY) SAMPLE#3	22	,#			143/Z7 DBC 2001	8	CAPPUCCIO	MACCAPI
	AVEBACE HIMIDITA	22	*			149/27 DEC 2001	3	CAPPUCCIO	MACCARI



Integrated Analytical Bulletin

Information Management System Labaratory

Condition: APPROVED

Males: COMPLETE

Sathlify Sharks 803002
PackTypes 30 ml PLASTIC BOTTLE

Bahch Manufactore Date: 17/05/2001

Storage Candition: 40/C/75% U.H. Time Labet 8 MONTHS

Preparation purpose: STABILITY

Pharmaceutical Development

Sample ID (Request No.) ; 20015440 User sample ID (lot) ; £33G62 Suffententental 115151

Mempha Dada: 30/11/2001

Smaple Type: SU010398 (PRAZEOS405D) CAPSLESO MG

Shakilly Shudy Start Date: \$1/05/2001

AXS975-MTM-0002

S.P.N. 2001005 - Manufachus PDAMMENACIA Nissings - API Beach

Samples Notes:

MACCAR HACCASE MACCAR MCCAR MOCAR MACCARI MACCARI MACCARI MACCARI MOCAR MCCAR Verifier CAPPUCCIO CAPPUDCIO CAPPUCCIO CAPPUCCIO CAPPUCCIO CAPPUCCIO CAPPUCCEO CAPPUCCIO CAPPUCCEO CAPPUCCIO CAPPLICCIO Analyst Lower lim_Upper lim Book-Data Analyses 45/27 DEC 2001 143/27 DEC 2001 4327 DEC 2001 143/27 DEC 2001 43/27 DEC 2001 143/27 DEC 2001 43/27 DEC 2001 148/27 DEC 2001 143/27 DEC 2001 43/27 DEC 2001 43.27 DEC 2004 90000 90.000 90008 80,000 80,000 60,000 80,000 80,000 Spec? M.C. Results 101.08 <u>8</u> 101.8 8 102.7 98.2 8 1,68 MAX. DISSOLUTION VALUE MIN. DISSOLUTION VALUE STANDARD DEVIATION DISSOLUTION SAMPLE #6 SAMPLE #2 SAMPLE #3 SAMPLE #4 SAMPLE #5 OSSEDSO1NO SAMPLE#1 Controls Method

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Integrated Analytical Bulletin

Laboratory Information Management System

Sample ID (Request No.): 20013449 Submission Id: 115151

User sample ID (lot); #25GD2

Swingle Type: SU310306 (PHU2010+ICAU) CAPSULE EO MG Sample Date: 90/11/2001

Babch Menulacians Data: 17/05/2001 Statistity Study: 183002

PREKTYPER 30 ml PLASTIC BOTTLE Storage Cendition: 40/C/70% LIF.
Thee Label: 6 MONTHS

Preparation purpose: STABILITY

APPROVED STATES COMPLETE

Statisting Study Start Date: 31/05/2001

S.P.P.L. 2001:005 - Menufackum FDAFHARBACIA Kembano - API Basa). (Aports-MTM-0002

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored hard getatin capsule containing yellow-orange powder

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05% Observations on the Method

Total correlated substances: 0.97%

0.86 0.51 0.51 1.03 1.24 1.89 1.89 Approved by: IMACCAPI
Approval date: 11-dec-2001

by MACCAR Printed 11-DEC-2001 10:29 AM

E / E Page



Integrated Analytical Bulletin

Laboratory Information Management System

Submission Id: 114395 Sample ID (Request No.) ; 20012535

User sample ID (lot) ; 183G0

Sample Date: 31/08/2/

Semple Type: SU0103 MG

Batch Manufacture Date: 17/05/2001 Stability Study: 183002

Condition: APPROVED Status: COMPLETE

Pack Type: 30 mi PLASTIC BOTTLE	Storage Condition: 25/C/60% U.R.	Time Label: 3 MONTHS	Preparation purpose: STABILITY
20.	72001	CASO (BA) (36001040) CABS II E FD	

	Stability Study Start Dale: 3105/2001
h	S.P.M. 2001005 - Manulacturer PD/PHAFMACIA Newlano - API Batch
	(A)5875-WTM-0002 Planettings-opposite and an independent of the contraction of the contra
	Samples Notes:

Method Controls Results M.U. Spec? Lower lim Upper lim Book-Data Analyses Analyst Verifier		Results	M.U.	Spec	Lowerlim	Upper lim	Lower lim Upper lim Book-Data Analyses	Analyst	Verifier
083GCO02#0 CAPSULE APPEARANCE	LE APPEARANCE	0=UNCHANGED	¥				(5441/27 SEP 2001	PASTO	MARIANI
CAPSUL	CAPSULE COLOR	0=UNCHANGED	Ħ				15441/27 SEP 2001	PASTO	MARIAN
CONTE	CONTENT APPEARANCE	0=UNCHANGED	ቜ				15441/27 SEP 2001	PASTO	MARIANI
CONTE	CONTENT COLOR	0=UNCHANGED	¥				15441/27 SEP 2001	PASTO	MARIANI
SMELL		0=UNCHANGED	ž				15441/27 SEP 2001	PASTO	MARIANI
083GT01#01_ (HPLC TITER) SAMPLE#1	IITER) SAMPLE#1	99.1	℀		000'06	- 110,000	15441/27 SEP 2001	PASTO	MARIAN
HPLC T	(HPLC TITER) SAMPLE#2	100.1	×		- 000'06	110.000	15441/Z7 SEP 2001	PASTO	MARIANI
(HPLC T	(HPLC TITER) SAMPLE#3	100.6	*		. 000'06	110.000	16441/27 SEP 2001	PAGTO	MARIAM
AVERAC	AVERAGE TITER (HPLC)	58,93	36		- 000:08	- 110,000	16441/27 SEP 2001	PASTO	MARIANI
83GSCO1#00 TOTAL (083GSC01#00 TOTAL CORRELATED SUBSTANCES 0.96	CES 0.96	*				15441/27 SEP 2001	PASTO	MARKANI
IMPURI	IMPURITIES NOT LESS THAN 0.05% SEE TEXT	35% SEE TEXT	3 €				15441/27 SEP 2001	PASTO	MARIANI
083GKF01#00 (HUMIDITY) SAMPLE#1	ITY) SAMPLE #1	1,5	×				16441/27 SEP 2001	PASTO	MARIAN
(HUMID)	(HUMIDITY) SAMPLE #2	1.9	38			•	15441/27 SEP 2001	PASTO	MARIANI
ідімірн)	(HUMIDITY) SAMPLE #3	4,1	*			•	15441/27 SEP 2001	PASTO	MARIAN
AVERAC	AVERAGE HUMIDITY	1,6	36			•	15441/27 SEP 2001	PASTO	MARIAN



Integrated Analytical Bulletin

Laboratory Information Marsagement System

Pharmaceutical Development

Sample Date: 31/08/2001 Sample ID (Request No.): 20012535 User sample ID (lot); 183G02 Submission id: 114395

Sample Type: SU010398 (PNU280940AD) CAPSULE 50

Batch Manufacture Date; 17/05/2001 Stability Study: 183G02

Pack Type: 30 mi PLASTIC BOTTLE Storage Condition: 25/C/90% U.R. Time Label: 3 MONTHS Preparation purpose: STABILITY

Condition: APPROVED

Status: COMPLETE

Stability Sludy Start Date: 31/05/2001

S.P.N. 2001005 - Manufacturer PD/PHARMACIA Narviano - API Batch (A)5975-MTM-0002

Samples Notes:

Wethod	Controls	nethalthur stationerum receipter Results	M.U.	Spec?	Lower lim	on new processors as a second contract of the	Applicated to the control of the con	arigat responses and military
					:			
3GDS01#01	GGDS01#01 SAMPLE #1	98.6	*		90,000	15441/31 SEP 2001	PASTO	MARIANI
	SAMPLE #2	95.1	*		80,000	15441/31 SEP 2001	PASTO	MARIANI
	SAMPLE #3	98.0	*		90.000	15441/31 SEP 2001	PASTO	MAHIANI
	SAMPLE #4	6.89	*		80,000	1644(/31 SEP 2001	PASTO	MARIAN
	SAMPLE #5	99.5	×		80.000	15441/31 SEP 2001	PASTO	MARIANI
	SAMPLE #6	87.8	38		90.000	15441/31 SEP 2001	PASTO	MARIANI
	DISSOLUTION	97,32	*		80.000	15441/31 SEP 2001	PASTO	MABIANI
	STANDARD DEVIATION	1,713	std-1			15441/81 SEP 2001	PASTO	MARIANI
	c.v.	1,76	3%			15441/31 SEP 2001	PASTO	MARIAN
	MIN. DISSOLUTION VALUE	95.1	æ		90,000	15441/31 SEP 2001	PASTO	MARIANI
	MAX. DISSOLUTION VALUE	296.5	*		80.000	15441/31 SEP 2001	PASTO	MARIAN



Integrated Analytical Bulletin

Information Management System Laborafary

Submission Id: 114395

Sample ID (Request No.) : 20012535

User sample ID (lot) ; 183G02

Sample Date: 31/08/2001

Sample Type: SU010388 (PNU280940AD) CAPSULE 50 MG

Batch Manufacture Date: 17/05/2001 Stability Study: 183602

Pack Type:30 ml PLASTIC BOTTLE

Storage Condition: 25/C/60% U.R. Time Label: 3 MONTHS Preparation purpose: STABILITY

Condition: APPROVED

Status: COMPLETE

Stability Study Start Date: 31/05/2001

S.P.N. 2001005 - Manufacturer PD/PHARMACIA Nervano - API Batch

(A)5975-MTM-0002

Samples Notes:

Observations on the Method 083GCO02#00, component: CAPSULE APPEARANCE

Opaque brick red colored hard gelatin capsule containing yellow-orange powder

083GDS01#01, component: DISSOLUTION Observations on the Method

average dissolution per single capsule after 15 minutes; 96.4% (C.Y. 1.5%) average dissolution per single capsule after 30 minutes; 96.4% (C.Y. 1.8%) average dissolution per single capsule after 45 minutes; 98.6% (C.Y. 1.6%)

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05% Observations on the Method

Correlated substances

BHT 0.683: 0.10% RHT 0.915: 0.05%

RRT 0.927:0.13% RRT 1,059:0.17%

HRT 1,092:0,08% RRT 1.254: 0.09%

RRT 1.265: 0.20% '

MARIAN

01-oct-2001 Approval date:



Pharmaceutical Development

Integrated Analytical Bulletin

Information Management System Laboratory

> Sample ID (Request No.) ± 20012537 Submission Id: 114397

Sample Date: 31/08/2001 User sample ID (lot) :: 183G02

Sample Type: SU010398 (PNU290940AD) CAPSULE 50 MG

Batch Manufacture Date: 17/05/2001 Stability Study: 183G02

Pack Typer 30 ml PLASTIC BOTTLE Storage Condition: 40×C/75% U.B. Time Label: 3 MONTHS Preparation purpose: STABILITY

Condition: APPROVED

Status: COMPLETE

(A)5975-MTM-0002 printenderminimate medical eminimate estructural estructural destructural estructural

Method Controls Results M.U. Spec? Lower lim Upper lim Book-Data Analyses Analyst Verifier	Controls	Results	M.U. Spec?	2? Lower lim Upper lim Book-Data Analyses	Book-Data Analyses	Analyst	Verifier
08390002#0	0839CC02#0 CAPSULE APPEARANCE	0=UNCHANGED	¥		15441/27 SEP 2001	PASTO	MARIANI
6	CAPSULE COLOR	0=UNCHANGED	Ħ		15441/27 SEP 2001	PASTO	MARIANI
	CONTENT APPEARANCE	0=UNCHANGED	¥		15441/27 SEP 2001	PASTO	MARIAN
	CONTENT COLOR	0=UNCHANGED	×		15441/27 SEP 2001	PASTO	MARIANI
	SMELL	0=UNCHANGED	¥		15441/27 8EP 2001	PASTO	MARIANI
OB3GTKO1#01_	OB3GTIO1#01_ (HPLC TITER) SAMPLE#1	90.6	3E	90,000 • 110,000	15441/27 SEP 2001	PASTO	MARIAN
so.	(HPLC TITER) SAMPLE#2	5.56	*	90,000 - 110,000	15441/27 SEP 2001	PASTO	MARIANI
	(HPLC TITER) SAMPLE#3	883	3%	90.000 - 110.000	15441/27 SEP 2001	PASTO	MARIANI
	AVERAGE TITER (HPLC)	B9.43	3¢	90.000 • 110.000	15441/27 SEP 2001	PASTO	MARIANI
083GSC01#00	083GSC01#00 TOTAL CORRELATED SUBSTA	STANCES 1.07	*		16441/27 SEP 2001	PASTO	MARIANI
	IMPURITIES NOT LESS THAN	AN 0.05% SEE TEXT	*		16441/27 SEP 2001	PASTO	MARIANI
083GKF01#00	083GKF01#CO (HUMIDITY) SAMPLE #1	4.9	*		15441/27 SEP 2001	PASTO	MARIANI
	(HUMIDITY) SAMPLE #2	2.1	*		15441/27 SEP 2001	PASTO	MARIANI
	(HUMIDITY) SAMPLE #3	2,0	3 ¢		15441/27 SEP 2001	PASTO	MARIAN
	AVERAGE HUMIDITY	63	3%		15441/27 SEP 2001	PASTO	MARIANI



Integrated Analytical Bulletin

Laboratory Information Management System

Pharmaceutical Development

Sample ID (Request No.) : 20012537 Submission id: 114397

Sample Date: 31/08/2001 User sample ID (lot) : 183G02

Sample Type: SU010398 (PNU290940AD) CAPSULE 50 MG

Batch Manufacture Date: 17/05/2001 Shability Study: 183902

Pack Type: 30 ml PLASTIC BOTTLE

Storage Condition: 40vG/75% U.A.
Time Label: 3 MONTHS
Preparation purpose: STABILITY

Candition: APPROVED

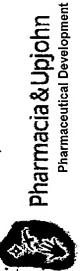
Status: COMPLETE

Stability Study Start Date: 31/06/2001

S.P.N. 2001005 - Manufacturer PD/PHARIMACIA Nerviano - API Batch

(A)5975-MTM-0002 Georgeanneai amb peachas and a thair deast's deastair deast deast deast de madery, agus de deastaire ma Samples Notes:

marke so an increase in a control of the control of	The substitution of the Results	M.U. Spec?	Lower lim Upp	rementarium marine in an experience of the second s	returnstured teather produced and Analyst	Verifier
083GDS01#01 SAMPLE #1	7.76	×	80.000	15441/31 SEP 2001	PASTO	MARIANI
SAMPLE #2	34.5	%	80.000	15441/31 SEP 2001	PASTO	MARIANI
SAMPLE #3	98.1	ž	80,000	15441/31 SEP 2001	PASTO	MARIANI
SAMPLE #4	95.1	*	80.000	15441/31 SEP 2001	PASTO	MARIANI
SAMPLE#5	93.1	햐	. 80,000	(5441/31 SEP 2001	PASTO	MARIANI
SAMPLE#6	100.1	%	90,000	15441/31 SEP 2001	PASTO	MARIANI
DISSOLUTION	96.43	*	80.000	15441/31 SEP 2001	PASTO	MARIANI
STANDARD DEVIATION	2.625	std-1		15441/31 SEP 2001	PASTO	MAHIANI
C.V.	2,72	*		15441/31 SEP 2001	PASTO	MARIANI
MIN. DISSOLUTION VALUE	94.5	**	80,000	15441/31 SEP 2001	PASTO	MARIANI
MAX. DISSOLUTION VALUE	100.1	*	80,000	15441/31 SEP 2001	PASTO	MARKANI



Integrated Analytical Bulletin

Monagement System Information Laboratory

Submission Id: 114397

Sample ID (Request No.) ; 20012537

User sample ID (tot) ; 183G02

Sample Date: 31/08/2001

Sumple Type: SU010398 (PNU290940AD) CAPSULE 50

Batch Menufacture Date: 17/05/2001 Stability Study: 183502

Pack Type: 30 ml PLASTIC BOTTLE Storage Condition: 40°C/75% U.R.

Time Label: 3 MONTHS Preparation purpose: STABILITY

COMPLETE Status :

Condition: APPROVED

Stability Study Start Date: 31/05/2001

S.P.N. 2001005 - Manufacturer PD/PHARMACIA Naviano - API Balch

(A)5975-MTM-0002

Samples Notes:

Observations on the Method 083GC002#00, component: CAPSULE APPEARANCE

Opaque brick red colored hard gelatin capsule containing yellow-orange powder

Observations on the Method 083GDS01#01, component: DISSOLUTION

average dissolution single determination after 15 minutes; 95.6% (C.V. 2.7%) average dissolution single determination after 30 minutes: 96.4% (C.V. 2.7%) average dissolution single determination after 45 minutes; 96.4% (C.V. 2.7%)

083GSC01#00, component: IMPURITIES NOT LESS THAN 0.05% Observations on the Method

Correlated substances

RRT 0.915; 0.07% RRT-0.926; 0.14% RRT 0.685: 0,11%

RRT 0.958; 0.07%

RRT 1.058: 0.16% RRT 1.080:0.08%

RRT 1.250: 0.09% RRT 1.262: 0.21% RRT 1.632: 0.14%

MARIANI Approved by:

01-oct-2001 Approval date:

> by MACCARI Printed 07-DEC-2001 08:32 AM

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